

REMARKS

I. Introduction

Further and favorable reconsideration is respectfully requested in light of the present amendments and the following remarks.

II. Status of the Claims

Claims 1-27, 29-39, 45-121 are pending. Claims 28 and 40-44 have been cancelled. Claims 1-22, 30, 32, 33, 46-116, and 121 have been withdrawn from consideration by the Examiner as being drawn to non-elective invention or species. Claims 23, 25, 29, 34, and 39 have been amended. Claim 23 has been amended to recite "the capsular bag of the eye" which has support in original claim 23. Claim 25 has been amended to recite only disulfide crosslinker which has support in original claim 28. Claims 29 and 34 have been amended to correct minor grammatical errors. Claim 39 has been amended to recite only oxidation by oxygen.

III. Summary of the Office Action

In the office action, the Examiner rejected

- 1) claims 23, 25, 44, 45, 117 and 118 under 35 U.S.C. § 102(b) as being anticipated by Sawhney (U.S. Patent No. 6,818,018);
- 2) claims 23-26, 29, 31, 34-36, 38-42, 44, and 45 under 35 U.S.C. § 102(e) as being anticipated by Hodd et al. (U.S. Patent No. 6,861,065);
- 3) claims 23-29, 31, 35-39, 44, 45, and 118-118 under 35 U.S.C. § 103(a) as being obvious over Marchant (U.S. Patent Application Publication No. 2002/0068087) in

view of Viegas et al. (U.S. Patent Application Publication No. 2003/0143274);

- 4) claims 24, 26-29, 31, and 34-39 under 35 U.S.C. § 103(a) as being obvious over Sawhney in view of Marchant.

No rejection has been applied to claims 119 and 120.

IV. Argument

A. THE CLAIMS ARE NOT ANTICIPATED

Claims 23, 25, 44, 45, 117 and 118 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Sawhney (U.S. Patent No. 6,818,018). Claims 1-22, 30, 32, 33, 46-116, and 121 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Hodd et al. (U.S. Patent No. 6,861,065). Applicant respectfully traverses the rejections.

To anticipate a claim, the reference must teach every element of the claim. *See* MPEP § 2131. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Sawhney fails to disclose every element of the claimed invention. In particular, Sawhney fails to disclose introduction of a reversible hydrogel solution into the capsular bag. The only application disclosed by Sawhney that relates to the eye is in Example 7 (Columns 23-24) where

the hydrogel is used as corneal shields. The reference suggests making contact lens from the hydrogel and rehydrating it for use as corneal shields. It is important to note that corneal shields “‘hug’ the eye like a contact lens and disappear after approximately 12 hours to 3 days.” Column 23, lines 63-65. In this application, it is apparent that the hydrogel covers the surface of the eye “like a contact lens” and is not permanent.

On the other hand, the present invention requires injecting the hydrogel solution into the capsular bag and *in situ* gelating the solution to form a lens replacement inside the capsular bag. This lens replacement is permanent and does not “disappear after approximately 12 hours to 3 days.” It is not desirable to have a patient go through surgery for lens replacement only to have the new lens disappear after 12 hours to 3 days.

Hodd et al. also fail to disclose every element of the claimed invention. In particular, Hodd et al. fail to disclose that 1) the hydrogel system contains a copolymer having a disulfide linker; and 2) the reversible hydrogel system is gelled by oxidization.

Hodd et al. disclose a method for lens replacement using *in situ* gelation of a polymer by photoinitiation. Because Hodd et al. use photoinitiation, their polymer is different from the present invention that uses oxidation to crosslink the polymers. The preferred crosslinking groups used by Hodd et al. are vinylic units, while the present invention uses a disulfide linker (which is not disclosed by Hodd et al.). The photoinitiation system used by Hodd et al. is not compatible with the presence of oxygen as its efficient crosslinking requires the absence of oxygen in order to take place (it is well known in the art that efficient crosslinking of vinylic units requires the absence of oxygen). Thus, it is not surprising that the disulfide linker is not disclosed by Hodd et al. as it is incompatible with photoinitiation.

Additionally, the hydrogel system of Hodd et al. is not reversible (nor does Hodd et al.

disclose a reversible system). The crosslinking of vinylic units is not reversible as its bonds are formed by photoinitiation and cannot be broken by the removal of light or light at a different wavelength. On the other hand, the disulfide hydrogel of the present invention is reversible. It forms a gel under oxidating conditions and dissociates into solution under reducing conditions. This is especially important when the artificial lens requires adjustment or replacement. For example, if the lens' index of refraction has to be changed, the lens of the present invention can be reduced to form a solution and the composition of the solution can be changed by adding materials (e.g. polymer, water, particles, etc.) and/or removing the solution. The solution can then be oxidized to form a new lens having a different refraction index. This is not possible with the hydrogel of Hodd et al.

Therefore, for the reasons noted, neither Sawhney nor Hodd et al. anticipates the present invention within the meaning of 35 U.S.C. § 102, because each reference fails to disclose every element of the claims. Accordingly, Applicant respectfully requests withdrawal of the rejection.

B. THE CLAIMS ARE NOT OBVIOUS

Claims 23-29, 31, 35-39, 44, 45, and 118-118 stand rejected under 35 U.S.C. § 103(a) as being obvious over Marchant (U.S. Patent Application Publication No. 2002/0068087) in view of Viegas et al. (U.S. Patent Application Publication No. 2003/0143274). Claims 24, 26-29, 31, and 34-39 stand rejected under 35 U.S.C. § 103(a) as being obvious over Sawhney in view of Marchant.

Marchant and Viegas et al., taken alone or in combination, do not disclose every element of the claimed invention. Marchant fails to disclose *in situ* gelation of a reversible hydrogel, i.e., gelation in a capsular bag. Marchant discloses bioadhesive hydrogels with degradable crosslink

“for use inside the body.” *See* paragraph [0021]. “For use inside the body,” however, is not the same as *in situ* gelation. The invention of Marchant requires making the hydrogel and then using it in the body, not gelating the hydrogel in the body (*in situ* gelation). The applications recited by Marchant do not contemplate *in situ* gelation. For example, the methods recited in paragraphs [0048]-[0050] and in paragraphs [0053]-[0055] recite a step of isolating the crosslinked composition. *In situ* gelation would not allow for the isolation of the crosslinked composition as the gel would already be in the body and its further purification (isolation) is not possible.

Additionally, Marchant discloses a degradable hydrogel. This is not compatible with the present invention where the gel is used a lens replacement. A degradable gel clearly is not desirable for use as a lens replacement as discussed above for Sawhney. This clearly teaches away from the present invention.

The Examiner relies on Viegas et al. to show uses of *in situ* formed gels. However, none of these uses pertains to lens replacement. In paragraphs [0049] and [0051] Viegas et al. disclose the used of the hydrogel as a corneal protective composition. This is not *in situ* lens replacement as discussed above for Sawhney. Thus, the combination of Marchant and Viegas et al does not disclose *in situ* gelation inside the capsular bag.

With regard to the rejection over Sawhney in view of Marchant. The deficiencies of these references are disclosed above. Their combination also does not cure those deficiencies. Therefore, their combination does not render the present invention obvious.

For the reasons noted, the present invention is not obvious within the meaning of 35 U.S.C. § 103. Accordingly, Applicant respectfully requests withdrawal of the rejection.

V. Conclusion

Applicants have responded to the Office Action mailed December 12, 2007. All pending claims are now believed to be allowable and favorable action is respectfully requested.

In the event that there are any questions relating to this Amendment or to the application in general, it would be appreciated if the examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

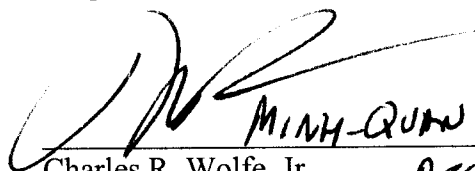
Please charge any shortage or credit any overpayment of fees to BLANK ROME LLP, Deposit Account No. 23-2185 (111828.0110). In the event that a petition for an extension of time is required to be submitted herewith and in the event that a separate petition does not accompany this response, Applicants hereby petition under 37 C.F.R. 1.136(a) for an extension of time for as many months as are required to render this submission timely.

Any fees due are authorized above.

Respectfully submitted,

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